5. 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the PreMarket Notification in accordance with the requirements of 21 CFR Part 807, Subpart E and Section 807.92.

1. Identification of Submitter:
Submitter: ClearView Diagnostics Inc.
Address: 371 Hoes Lane Suite 104
Piscataway, NJ 08854
Phone: 732-529-5755
Fax: 732-529-5757
Contact: Christine Podilchuk
Title: CEO
Phone: 908-616-1945
Fax: 732-529-5757
Summary Date: January 16, 2014

2. Identification of Product:
Device Name: ClearViewHD, Version 1.0
Device Common Name: Image Enhancement System
Device Classification: 21 CFR 892.2050, Class II, LLZ (90)
Classification Name: Image Processing, System
Manufacturer: ClearView Diagnostics Inc.

3. Marketed Devices
The ClearViewHD System provides post-acquisition image processing of ultrasound images and automatically generates an enhanced image with reduced speckle noise and improved contrast enhancement for viewing and diagnosing. In terms of safety, ClearViewHD is substantially equivalent to the currently marketed post-processing software products that analyze data from medical images. In terms of safety and performance, this software medical device is substantially equivalent to the devices listed below:

Model: SharpView
Manufacturer: ContextVision AB
510(k) Number: K993802, K024028

Model: Sapheneia Clarity
Manufacturer: Sapheneia Commercial Products AB
510(k) Numbers: K063391

4. Device Description

The ClearViewHD image processing software reduces noise and enhances contrast of medical ultrasound images. The software is a Windows XP or higher, Windows Embedded, and DICOM-compatible platform that may be installed on a standalone PC, laptop, *or* tablet The software does not require any specialized hardware but the time to process an image will vary depending on the hardware specifications. ClearViewHD is based on a core noise reduction and contrast enhancement algorithm that uses novel statistical techniques to determine whether each pixel location is due to mostly noise or signal (tissue structure) and attenuates the regions due to noise while preserving and accentuating the regions due to tissue structure. The statistical method is based on the a priori knowledge that the ultrasound signal is sparse and compressive sampling theory can be used to reconstruct the signal with fewer samples than the Nyquist Rate specifies.

The ClearViewHD image processing software is a DICOM node that accepts DICOM3.0 digital medical files from an ultrasound device or another DICOM source. ClearViewHD processes the image and returns the original and/or enhanced image to another DICOM node such as a specific PC/workstation or the PACS system. The ClearViewHD software is designed to be compatible with any of the DICOM-compliant medical devices distributed by various OEM vendors.

5. Indications for Use

The ClearView Image Enhancement System is intended for use by a qualified technician or diagnostician to reduce speckle noise, enhance contrast and transfer ultrasound images. The software provides a DICOM-compliant ClearViewHD-enhanced image along with the original ultrasound image to assist in image interpretation by the trained physician.

ClearViewHD is a software application designed to reduce speckle noise and enhance contrast in medical ultrasound images that are viewed for diagnosis. The software provides a ClearViewHD-enhanced image along with the original ultrasound image for viewing by the trained diagnostician in order to assist in image interpretation and diagnosis. The enhanced image along with the original image may be sent to any other DICOM node. The output is provided in standard DICOM format as an additional series with appropriate descriptors so that it can be displayed on most third-party commercial DICOM workstations. ClearViewHD is intended to be used by physicians and technicians skilled in diagnostic ultrasound imaging.

6. Substantial Equivalence Chart

Product	**SharpView (K024028,K993802)**	**Sapheneia Clarity (K063391)**	**ClearViewHD**
Characteristics	Software for transfer,	Software for transfer,	Software for transfer and

	storage, enhancement and viewing of multimodal medical images.	storage, noise reduction, contrast enhancement and viewing of multimodal medical images.	enhancement of ultrasound images.
Intended Use	The Image Enhancement System is intended for use by a qualified technologist for transfer storage, enhancement, and viewing of multimodal images.	The Sapheneia Clarity is intended for use by radiologists for transfer, storage, noise reduction, contrast enhancement and viewing of multi-modality images from a variety of diagnostic systems	ClearViewHD is intended for use by a qualified technologist for transfer and enhancement of ultrasound images from a variety of diagnostic systems.
Physical Characteristics	Software Package Operates on off-the-shelf hardware	Software Package Operates on off-the-shelf hardware	Software Package Operates on off-the-shelf hardware
Computer	PC compatible	PC compatible	Same
Operating System	Windows 98, NT4.0, 2000 and XP	Windows	Windows XP and higher, Windows Embedded
Storage	Hard disk or any compatible PC Method: Optical, CDROM, ...		Storage not supported
Image Input	DICOM3.0	DICOM3.0	DICOM3.0

7. Non-Clinical Performance Data

Bench testing on phantoms as well as previously collected clinical images resulted in a reduction in speckle noise energy yielding an average improvement in Signal-to-Noise Ratio (SNR) of 12 dB on 10,000 simulated A-Scans using ClearViewHD. Likewise the Contrast-to-Noise Ratio (CNR) after applying ClearViewHD to the ultrasound images resulted in an average improvement of 2 times the original CNR. ClearViewHD enhanced images were also viewed with the original image and found to visually contain less speckle noise and enhanced contrast. These metrics as well as visual inspection confirm the ability of the ClearViewHD Software Product to reduce speckle noise and enhance contrast.

8. Conclusion

After analyzing bench testing data, it is the conclusion of ClearView Diagnostics that the ClearViewHD Image Enhancement System is as safe and effective as the predicate devices, has few technological differences, and only a minor change to the indications for use and not supporting storage and viewing compared with the predicate devices, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 28, 2014

Clearview Diagnostics, Inc.
% Ms. Christine Podilchuk
President
371 Hoes Lane Suite 104
PISCATAWAY NJ 08854

Re: K140139
Trade/Device Name: ClearViewHD
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 15, 2014
Received: April 22, 2014

Dear Ms. Podilchuk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140139

Device Name
ClearViewHD

Indications for Use *(Describe)*
The ClearView Image Enhancement System is intended for use by a qualified technician or diagnostician to reduce speckle noise, enhance contrast, and transfer ultrasound images. The software provides a DICOM-compliant ClearViewHD-enhanced image along with the original ultrasound image to assist in image interpretation by the trained physician.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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